records for all of the fees involved pursuant to § 20.42.

§ 20.52 Request for review without copying.

(a) A person requesting disclosure of records shall be permitted an opportunity to review them without the necessity for copying them where the records involved contain only disclosable data and information. Under these circumstances, the Food and Drug Administration will charge only for the costs of searching for the records.

(b) Where a request is made for review of records without copying, and the records involved contain both disclosable and nondisclosable information, the records containing nondisclosable information shall first be copied with the nondisclosable information blocked out and the Food and Drug Administration will charge for the costs of searching and copying.

§ 20.53 Indexing trade secrets and confidential commercial or financial information.

Whenever the Food and Drug Administration denies a request for a record or portion thereof on the grounds that the record or portion thereof is exempt from public disclosure as trade secret or confidential commercial or financial data and information under § 20.61, and the person requesting the record subsequently contests the denial in the courts, the Food and Drug Administration will so inform the person affected, i.e., the person who submitted the record, and will require that such person intervene to defend the exempt status of the record. If a court requires the Food and Drug Administration to itemize and index such records, the Food and Drug Administration will so inform the person affected and will require that such person undertake the itemization and indexing of the records. If the affected person fails to intervene to defend the exempt status of the records and to itemize and index the disputed records, the Food and Drug Administration will take this failure into consideration in deciding whether that person has waived such exemption so as to require the Food and Drug Administration to promptly make the records available for public disclosure.

[42 FR 15616, Mar. 22, 1977, as amended at 59 FR 535, Jan. 5, 1994]

Subpart D—Exemptions

§ 20.60 Applicability of exemptions.

(a) The exemptions established in this subpart shall apply to all Food and Drug Administration records, except as provided in subpart E of this part. Accordingly, a record that is ordinarily available for public disclosure in accordance with the provisions in subpart F of this part or of another regulation cross-referenced in § 20.100(c) is not available for such disclosure to the extent that it falls within an exemption contained in this subpart, except as provided by the limitations on exemptions specified in subpart E of this part. For example, correspondence that is ordinarily disclosable under § 20.103 is not disclosable to the extent that it contains trade secrets exempt from disclosure under § 20.61 and is not subject to discretionary release under § 20.82.

(b) Where application of one or more exemptions results in a record being disclosable in part and nondisclosable in part, the rule established in § 20.22 shall apply.

§ 20.61 Trade secrets and commercial or financial information which is privileged or confidential.

(a) A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.

(b) Commercial or financial information that is privileged or confidential means valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs.

(c) Data and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure.

(d) A person who submits records to the Government may designate part or all of the information in such records as exempt from disclosure under exemption 4 of the Freedom of Information Act. The person may make this designation either at the time the records are submitted to the Government or within a reasonable time thereafter. The designation must be in writing. Where a legend is required by a request for proposals or request for quotations, pursuant to 48 CFR 352.215–12, then that legend is necessary for this purpose. Any such designation will expire 10 years after the records were submitted to the Government.

(e) The procedures in this paragraph apply to records on which the submitter has designated information as provided in paragraph (d) of this section. These procedures also apply to records that were submitted to the Food and Drug Administration when the agency has substantial reason to believe that information in the records could reasonably be considered exempt under exemption 4 of the Freedom of Information Act. Certain exceptions to these procedures are set forth in paragraph (f) of this section.

(1) When the Food and Drug Administration receives a request for such records and determines that disclosure may be required, the Food and Drug Administration will make reasonable efforts to notify the submitter about these facts. The notice will include a copy of the request, and it will inform the submitter about the procedures and time limits for submission and consideration of objections to disclosure. If the Food and Drug Administration must notify a large number of submitters, notification may be done by posting or publishing a notice in a place where the submitters are reasonably likely to become aware of it.

(2) The submitter has 5 working days from receipt of the notice to object to disclosure of any part of the records and to state all bases for its objections.

(3) The Food and Drug Administration will give consideration to all bases that have been stated in a timely manner by the submitter. If the Food and Drug Administration decides to disclose the records, the Food and Drug Administration will notify the submitter in writing. This notice will briefly explain why the agency did not sustain the submitter's objections. The Food and Drug Administration will include with the notice a copy of the records about which the submitter objected, as the agency proposes to disclose them. The notice will state that the Food and Drug Administration intends to disclose the records 5 working days after the submitter receives the notice unless a U.S. District Court orders the agency not to release them.

(4) If a requester files suit under the Freedom of Information Act to obtain records covered by this paragraph, the Food and Drug Administration will promptly notify the submitter.

(5) Whenever the Food and Drug Administration sends a notice to a submitter under paragraph (e)(1) of this section, the Food and Drug Administration will notify the requester that the Food and Drug Administration is giving the submitter a notice and an opportunity to object. Whenever the Food and Drug Administration sends a notice to a submitter under paragraph (e)(3) of this section, the Food and Drug Administration will notify the requester of this fact.

(f) The notice requirements in paragraph (e) of this section do not apply in the following situations:

(1) The Food and Drug Administration decided not to disclose the records;

(2) The information has previously been published or made generally available;

(3) Disclosure is required by a regulation issued after notice and opportunity for public comment, that specifies narrow categories of records that are to be disclosed under the Freedom of Information Act, but in this case a submitter may still designate records as described in paragraph (d) of this section, and in exceptional cases, the Food and Drug Administration may, at its discretion, follow the notice procedures in paragraph (e) of this section;

(4) The information requested has not been designated by the submitter as exempt from disclosure when the submitter had an opportunity to do so at the time of submission of the information or within a reasonable time thereafter, unless the Food and Drug Administration has substantial reason to believe that disclosure of the information would result in competitive harm; or

(5) The designation appears to be obviously frivolous, but in this case the Food and Drug Administration will still give the submitter the written notice required by paragraph (e)(3) of this section (although this notice need not explain our decision or include a copy of the records), and the Food and Drug Administration will notify the requester as described in paragraph (e)(5) of this section.

[42 FR 15616, Mar. 22, 1977, as amended at 59 FR 535, Jan. 5, 1994]

§ 20.62 Inter- or intra-agency memoranda or letters.

All communications within the Executive Branch of the Federal government which are in written form or which are subsequently reduced to writing may be withheld from public disclosure except that factual information which is reasonably segregable in accordance with the rule established in § 20.22 is available for public disclosure.

§ 20.63 Personnel, medical, and similar files, disclosure of which constitutes a clearly unwarranted invasion of personal privacy.

(a) The names or other information which would identify patients or research subjects in any medical or similar report, test, study, or other research project shall be deleted before the record is made available for public disclosure.

(b) The names and other information which would identify patients or research subjects should be deleted from any record before it is submitted to the Food and Drug Administration. If the Food and Drug Administration subsequently needs the names of such individuals, a separate request will be made.

(c) Requests for deletion of business or product names prior to disclosure of any record to the public shall not be granted on the ground of privacy, but such deletion may be justified under another exemption established in this subpart, e.g., the exemption for trade secrets and confidential commercial or financial information under § 20.61.

(d) Names of individuals conducting investigations, studies, or tests on products or ingredients shall not be deleted prior to disclosure of any record to the public unless extraordinary circumstances are shown.

(e) A request for all records relating to a specific individual will be denied as a clearly unwarranted invasion of personal privacy unless accompanied by the written consent of the individual named.

(f) The names and any information that would identify the voluntary reporter or any other person associated with an adverse event involving a human drug, biologic, or medical device product shall not be disclosed by the Food and Drug Administration or by a manufacturer in possession of such reports in response to a request, demand, or order. Information that would identify the voluntary reporter or persons identified in the report includes, but is not limited to, the name, address, institution, or any other information that would lead to the identities of the reporter or persons identified in a report. This provision does not affect disclosure of the identities of reporters required by a Federal statute or regulation to make adverse event reports. Disclosure of the identities of such reporters is governed by the applicable Federal statutes and regulations.

(1) *Exceptions.* (i) Identities may be disclosed if both the voluntary reporter and the person identified in an adverse event report or that person's legal representative consent in writing to disclosure, but neither FDA nor any manufacturer in possession of such reports shall be required to seek consent for disclosure from the voluntary reporter or the person identified in the adverse event report or that person's legal representative; or

(ii) Identities of the voluntary reporter and the person who experienced the reported adverse event may be disclosed pursuant to a court order in the course of medical malpractice litigation involving both parties; or (iii) The